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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/759,130	01/12/2001	Christopher C. Fraser	MPI00-535OMNIM	2853

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EXAMINER
JIANG, DONG

ART UNIT	PAPER NUMBER
1646	

DATE MAILED: 06/19/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/759,130	FRASER ET AL.	
	Examiner	Art Unit	
	Dong Jiang	1646	

-- The MAILING DATE of this communication app ars on the cov r sheet with the correspond nce addr ss --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 April 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *86-101* is/are pending in the application.

4a) Of the above claim(s) *93-96* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *86-92 and 97-101* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *86-101* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *3, 5 & 6* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED OFFICE ACTION

Applicant's election without traverse of Invention A, represented by the original claims 1-7, 12 and 26-55, in Paper No. 17 is acknowledged. Applicant's sequence election with traverse of SEQ ID NO:379 and 381 in Paper No. 17 is acknowledged. The traversal is on the ground(s) that SEQ ID NOs:379 and 380 should be examined together as they are related in that SEQ ID NO:380 comprises a portion of (ORF) full length sequence of SEQ ID NO:379, and therefore, the inclusion of both sequences in the election does not pose a serious burden on the Examiner. This argument is persuasive, and accordingly, the restriction requirement between SEQ ID NO:379 and 380 is withdrawn.

Applicant's preliminary amendment in paper No. 17 is acknowledged and entered. Following the amendment, the original claims 1-85 are canceled, and the new claims 86-101 are added.

Currently claims 86-101 are pending, and claims 86-92 and 97-101 are under consideration. Claims 93-96 are withdrawn from further consideration as being drawn to a non-elected invention.

The references listed on the PTO-1449 in paper No. 3 are not present in the current application file. In response to this Office Action only, applicants may submit another set of the same references, and the Examiner will consider them as though they were submitted with IDS in paper No. 3.

The information disclosure statement filed 24 May 2001 fails to comply with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609 because the references are not listed in a proper format as they are not listed separately from the statement, there is no place for the Examiner's initials indicating the consideration, and each item comprises multiple references. It has been placed in the application file (as paper No. 5), but the information referred to therein has not been considered as to the merits. Applicant is advised to re-submit the IDS in a proper format (see MPEP 609, 600-134 to 600 136) with the copies of the references, and that the date of any re-submission of any item of information contained in this information disclosure statement or the submission of any missing element(s) will be the date of submission for

purposes of determining compliance with the requirements based on the time of filing the statement, including all certification requirements for statements under 37 CFR 1.97(e). See MPEP § 609 ¶ C(1).

Formal Matters:

Priority

This application claims priority to US applications 09/479,249, 09/559,497, 09/578,063, 09/333,159, 09/596,194, 09/342,364, 09/608,452, 09/393,996, 09/608,871 and 09/420,707. For the following reasons, the Examiner finds that the present claims are not supported in the manner required by 35 U.S.C. 101 and 112, first paragraph by the prior applications, thus none of present claims is entitled to the benefit of the filing date of any of the prior applications.

The priority applications merely discloses the three sequences: nucleic acids of SEQ ID NO:379 and 380 encoding the polypeptide of SEQ ID NO:381. The prior applications fails to provide any specific and substantial utility for the nucleic acids or the polypeptide encoded thereby, and provides no guidance or working examples to teach how to used the claimed invention. Therefore, the Examiner is not able to establish that the priority document satisfies the utility/enablement requirement of 35 U.S.C. 101/112, first paragraph. As such, the claims of the instant application are not entitled to the benefit of the filing date of prior applications listed above.

Title

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the elected claims are directed.

Objections and Rejections under 35 U.S.C. §101 and §112:

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 86-92 and 97-101 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by a credible, substantial, specific, or well-established utility.

Claims 86-92 and 97-101 are directed to an isolated nucleic acids of SEQ ID NO:379 and 380 encoding a human polypeptide of SEQ ID NOs:381, variants and fragments thereof, a vector containing said nucleic acid, a host cell thereof, and a recombinant method of producing the polypeptide. Said polypeptide is designated TANGO234.

The specification discloses that there is the conservation of amino acid sequence between human TANGO234 protein and bovine WC1 protein (page 236, lines 11-12), which is a ruminant protein having SRCR domain and is involved in modulating gamma delta T cell activity (page 244, lines 7-20), that TANGO234 has domains homologous to speract receptor repeated (SRR) domain and scavenger receptor cysteine-rich (SRCR) domain (page 242, lines 4-5), thus, TANGO234 is involved in one or more physiological processes in which these other SRR or SRCR domain-containing proteins are involved, such as cholesterol deposition, atherogenesis and other vascular and cardiovascular disorders (page 243, lines 18-20, and page 247, the last paragraph), infection and immune responses (page 244, lines 2-6). Further, the specification asserts that TANGO234 is likely the human orthologue of ruminant protein WC1 based on the sequence homology, and thus is involved with the same physiological processes described for WC1 in human (page 244, lines 21-22), and in modulating growth, proliferation, survival, differentiation and activity of gamma delta T cells (page 247, lines 17-20) and other cells where TANGO234 is expressed, and that TANGO234 has a role in disorders involve these cells (page 247, lines 3-14).

The asserted utilities discussed above are not considered to be substantial because such assertion is based on the sequence homology of human TANGO234 protein with a known protein. Such prediction based upon sequence similarity to known proteins cannot be accepted in the absence of supporting evidence, because it is well known that many proteins belong to a same family, share a high degree of sequence similarity, yet have diverse, and sometimes even opposite biological activities and functions. For example, in the transforming growth factor (TGF) family, Vukicevic et al. (1996, PNAS USA 93:9021-9026) disclose that OP-1, a member of the TGF-family of proteins, has the ability to induce metanephrogenesis, whereas closely related TGF- family members BMP-2 and TGF-1 had no effect on metanephrogenesis under

identical conditions (p. 9023, paragraph bridging columns 1-2). Additionally, Skolnick et al. (Trends in Biotechnology, 2000) teaches that because proteins can have similar structures but different functions, determining the structure of a protein may not necessarily reveal its function (see entire article, especially Box 2). Brenner (1999, Trends in Genetics 15:132-133) argues that accurate inference of function from homology must be a difficult problem since, assuming there are only about 1000 major gene superfamilies in nature, then most homologues must have different molecular and cellular functions. Therefore, in the absence of any actual experimental confirmation of any of biological properties, the skilled artisan would not accept the asserted activity as being substantial.

Therefore, each of the disclosed utilities requires additional knowledge about the claimed nucleic acids and the protein encoded thereby before the nucleic acids or protein can be used for a specific purpose, such as those set forth in the specification. The specification does not provide any of such specific information about SEQ ID NO:379-381. The disclosed uses are not sustantial, in the absence of knowledge of the substrate which said TANGO234 actually bind, any disclosed gene mutation, or any disease or condition which could be so diagnosed, or treated. Therefore, there is no immediately available patentable utility for TANGO234 or nucleic acids encoding such. Upon further research, a substantial utility might be found for the claimed isolated nucleic acids. This further characterization, however, is part of the act of invention, and until it has been undertaken, the claimed invention is incomplete.

The instant situation is analogous to that which was addressed in *Brenner v. Manson*, 148 U.S.P.Q. 689 (1966), in which a novel compound which was structurally analogous to other compounds which were known to possess anti-tumor activity was alleged to be potentially useful as an anti-tumor agent in the absence of evidence supporting this utility. The court expressed the opinion that all chemical compounds are "useful" to the chemical arts when this term is given its broadest interpretation. However, the court held that this broad interpretation was not the intended definition of "useful" as it appears in 35 U.S.C. §101, which requires that an invention must have either an immediately apparent or fully disclosed "real world" utility. The court held that:

> The basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an

> invention with substantial utility. . . . [u]nless and until a process is refined and developed to this point-where specific benefit exists in currently available form-there is insufficient justification for permitting an applicant to engross what may prove to be a broad field. ... a patent is not a hunting license. ... [i]t is not a reward for the search, but compensation for its successful conclusion.

The instant claims are drawn to a polypeptide of as yet undetermined function or biological significance. There is no evidence of record or any line of reasoning that would support a conclusion that the claimed nucleic acids encoding the TANGO234 was, as of the filing date, useful for any uses as claimed. Until some actual and specific biological significance can be attributed to the nucleic acids, and the polypeptide identified in the specification as TANGO234, one of ordinary skill in the art would be required to perform additional experimentation in order to determine how to use the claimed invention. Thus, there was no immediately apparent or "real world" utility and the claimed invention is incomplete as of the filing date.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 86-92 and 97-101 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a credible asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Further, even if the specification taught how to use human TANGO234, enablement would not be commensurate in scope with claims 86, 97, and the dependent claims 88-92 and 98-101, which encompass % variants of the nucleic acid (claim 86, part a), claim 99, for example), fragments of SEQ ID NO:379 or 380 (claims 86, parts b), d) and e), and claim 97, part b), for example), allelic or hybridization variants of SEQ ID NO:381 (claim 86, part f), and claim 97, part c), for example).

The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make/use the invention commensurate in scope with the claims. The specification discloses merely *one* human TANGO234 with SEQ ID NO:381 and the nucleic acids encoding such with SEQ ID NO: 379 or 380. No other TANGO234 variants or fragments meeting the limitations of these claims were ever identified or particularly described. The specification provides neither guidance, nor working example to teach how to make any of variants or fragments of TANGO234. Since a biological function of TANGO234 is not disclosed in the specification, and since one skilled in the art could not determine with a reasonable expectation of success what a biological function of TANGO234 would be, the skilled artisan would not be able to make TANGO234 variants or fragments, and test them for a biological activity, because one is not disclosed. Furthermore, the specification provides no guidance as to how the skilled artisan could use an inactive TANGO234 variant or fragment, as *no functional limitation* associated with the TANGO234 variants or fragments in the claims (claims 8, 24, and 30, for example). Therefore, it would require undue experimentation to practice this invention as claimed, because the skilled artisan would have no reasonable expectation of being able to use the TANGO234 variants or fragments for any purpose stated in the specification. With respect to the hybridization variants, it is well known in the art that hybridization will occur even under highly stringent conditions if there is only local identity between two molecules whose sequences might be totally divergent outside of that region, and hybridization would be expected to occur under low stringent conditions if two molecules share only certain degree of sequence homology. Such hybridized molecules may encode proteins having distinct biological functions from those of the SEQ ID NO:381. Therefore, it would require undue experimentation in order to use the claimed invention in its full scope. Further, as there is not functional limitation associated with the polypeptides encoded by the claimed polynucleotides, the specification has not taught a skilled artisan how to use the polypeptides encoded by the hybridization variants, and not sharing functional properties with TANGO234.

Claims 86, 97 and 99 are further rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to a nucleic acid at least 90% or 95% identical to a particular disclosed sequence, or a nucleic acid encoding a naturally occurring *allelic variant* and hybridizing with a particular disclosed sequence. The claims do not require that the polypeptide possess any particular biological activity, nor any particular conserved structure, or other disclosed distinguishing feature. Thus, the claims are drawn to a genus of nucleic acids including those encoding polypeptides that is defined only by sequence identity.

To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of compete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. In this case, the only factor present in the claim is a partial structure in the form of a recitation of percent identity. There is not even identification of any particular portion of the structure that must be conserved. Accordingly, in the absence of sufficient recitation of distinguishing identifying characteristics, the specification does not provide adequate written description of the claimed genus.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116). As discussed above, the skilled artisan cannot envision the detailed chemical structure of the encompassed genus of polypeptides, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The compound itself is required.

See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483. In *Fiddes*, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence.

Therefore, only isolated nucleic acids of SEQ ID NO:379, 380, and those encoding the amino acid sequence of SEQ ID NO:381, but not the full breadth of the claims meets the written description provision of 35 U.S.C. §112, first paragraph. This is particularly important in absence of a specific known activity. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

Claims 86, 87, 97 and 99 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claims 86, 87, 97 and 99 state a deposit of a DNA clone encoding said protein contained in ATCC Deposit No. 207184. However, the specification fails to provide the deposit statement indicating the deposit material will be readily available to the public without restriction upon issuance of the patent. Such statement would satisfy the enablement requirement of 35 U.S.C. 112.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 86-92 and 97-101 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 86 is indefinite for the recitation in part d), which recites "a polypeptide comprising the amino acid sequence of any of SEQ ID NOs:379, 380, and ...", as SEQ ID

NO:379 and 380 are nucleic acid sequences, not amino acid sequences. The claim is further indefinite because it is unclear what "any of the *clones* deposited as ATCC Accession number 207184" in part f) is meant as ATCC 207184 merely represents one single clone. Further, the claim is incomplete for omitting essential elements. Part f) of the claim is limited by a hybridization method under stringency conditions. The specification does not define such conditions. As the target sequence is specific, an artisan needs to know the specific corresponding hybridization conditions in order to practice the claimed invention. The claim recites neither hybridization conditions to ensure that any hybridized polynucleotides will comprise specific sequence within the meaning of the disclosure, nor process steps which would effect the removal of nonspecific hybridization complexes. Without knowing what conditions are comprised by "stringent conditions", one can not determine the metes and bounds of nucleic acids within the limitations of the claim.

Claims 87, 97 and 99 are similarly indefinite for the recitation of "any of the *clones*".

Claim 97 is similarly indefinite for the recitation of "under stringent conditions" in part c) for the same reasons above.

Claim 91 recites the limitation "*the* host cell of claim 86". There is insufficient antecedent basis for this limitation in the claim.

The remaining claims are rejected for depending from an indefinite claim.

Rejections Over Prior Art:

The following rejections under 35 U.S.C. § 102 and 103 are made in view of the determination **that the effective filing date for the instantly claimed invention is 1/12/2001, which is the actual filing date of the present application.**

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 86, 88, 90, 99 and 101 are rejected under 35 U.S.C. 102(a) as being anticipated by Gronlund et al. (Locus AF264014, GenEmbl, 28 November 2000; and J. Immunol., 2000, 165:6406-15).

Gronlund discloses a nucleotide sequence, locus AF264014, which comprises nucleotides 21-4581 of SEQ ID NO:379 of the present invention with 99.8% sequence similarity, and encodes a human M160 polypeptide having 99.7% sequence similarity to the amino acid sequence of SEQ ID NO:381 of the present invention (Figure 2, and see computer printout of the search results). Further, Gronlund teaches that M160 polypeptide comprises SRCR domain (the abstract). The cited sequences therefore, anticipates the present claims 86, 99 and 101 as being a nucleic acid molecule comprising at least 300 nucleotide residues and having a nucleotide sequence identify to at least 300 consecutive nucleotide residues of SEQ ID NO:379 (claim 86), a nucleic acid at least 90% identical to SEQ ID NO:380 (claim 86), or a nucleic acid encoding a polypeptide at least 95% identical to the amino acid sequence of SEQ ID NO:381 (claim 99) and comprising a SRCR domain (claim 101). Additionally, the reference teaches a vector, PCRIIvector containing the cited nucleic acid sequence, and a host cell thereof, INVaF' (page 6408, under "*Long-range PCR*"). Therefore, the reference also anticipates claims 88 and 90 of the instant invention.

Claims 86, 88 and 90 are rejected under 35 U.S.C. 102(b) as being anticipated by locus AI095706 reported by NCI-CGAP (EST, 05 October 1998).

Locus AI095706 comprises nucleotides 4094-4413 of SEQ ID NO:379 of the present invention with 100% sequence identity (see computer printout of the search results). The cited sequences therefore, anticipates the present claim 86 as being a nucleic acid molecule comprising at least 300 nucleotide residues and having a nucleotide sequence identify to at least 300 consecutive nucleotide residues of SEQ ID NO:379. Additionally, the reference teaches a vector (pT7T3) containing the cited nucleic acid sequence, and a host cell thereof, DH10B, and therefore, it also anticipates claims 88 and 90 of the instant invention.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claim 89 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gronlund et al. (Locus AF264014, GenEmbl, 28 November 2000; and J. Immunol., 2000, 165:6406-15), as applied to claims 86, 88, 90, 99 and 101 above, and further in view of Capon et al., US5,116,964.

The teachings of Gronlund are reviewed above. The primary reference does not teach the nucleic acid further comprising nucleic acid encoding a heterologous polypeptide.

Capon discloses a novel polypeptide comprising an immunoglobulin Fc region, and a target protein sequence (column 5, lines 13-20). The cited reference indicates that fusion of a target protein to a stable plasma protein such as an immunoglobulin constant domain extends the in vivo plasma half-life, and facilitate purification of the protein (column 4, lines 38-43, and column 5, lines 13-20).

It would have been obvious to the person of ordinary skill in the art at the time the invention was made to modify the nucleic acid of Gronlund by adding a sequence encoding a heterologous polypeptide to make a fusion polypeptide comprising said peptide and an Ig constant region sequence as taught by Capon. One of ordinary skill in the art would have been motivated to make such a fusion polypeptide for the advantages taught by Capon, and reasonably

would have expected success in view of Capon's disclosure, in which various genes had already been expressed successfully in their systems at the time the invention was made.

Claims 91, 92 and 97 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gronlund et al. (Locus AF264014, GenEmbl, 28 November 2000; and J. Immunol., 2000, 165:6406-15), as applied to claims 86, 88, 90, 99 and 101 above, and further in view of in view of Sibson et al., WO94/01548.

The teachings of the primary reference are summarized above. The primary reference does not specifically teach a mammalian host cell or a non-human mammalian host cell containing the nucleic acid, and a method for recombinantly producing the encoded polypeptide.

Sibson discloses that it is generally useful to place a desired cDNA sequence into an expression vector, host cell, and express the encoded protein, and that prokaryotic, and lower or higher eucaryotic hosts may be selected as the host for expression and higher eucaryotes may be preferred to ensure correct modifications (pages 8-11). It would have been obvious to the person of ordinary skill in the art at the time the invention was made to use mammalian host cell containing the vector taught by Gronlund to produce said polypeptide using the recombinant method taught by Sibson. The person of ordinary skill in the art would have been motivated to do so in view of Sibson's suggestion that it would be desirable to do so, and reasonably would have expected success because Sibson has demonstrated such a process, and the mammalian host cell and the method steps of recombinant expression of a polypeptide have been well established in the art and conventionally practiced in the field.

Conclusion:

No claim is allowed.

Advisory Information:

Any inquiry concerning this communication should be directed to Dong Jiang whose telephone number is 703-305-1345. The examiner can normally be reached on Monday - Friday from 9:30 AM to 7:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (703) 308-6564. The fax phone number for the organization where this application or proceeding is assigned is 703-308-0234.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Lorraine Spector
LORRAINE SPECTOR
PRIMARY EXAMINER

Dong Jiang, Ph.D.
Patent Examiner
AU1646
6/9/03